IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

GENUS LIFESCIENCES INC,

Plaintiff,

vs.

MALLINCKRODT LLC and SPECGX LLC

Defendants.

C.A. No. 5:19-cv-05403-JMY

JURY TRIAL DEMANDED

COMPLAINT

Genus Lifesciences Inc. ("Genus" or "Plaintiff"), by its undersigned attorneys, for its Complaint against defendants Mallinckrodt LLC and SpecGx LLC (collectively, "Mallinckrodt" or "Defendants"), alleges as follows:

PRELIMINARY STATEMENT

1. This is a civil action arising under the Defend Trade Secrets Act, 18 U.S.C. § 1836, as amended, based on Mallinckrodt's misappropriation of Genus's trade secrets, and under the laws of the Commonwealth of Pennsylvania and/or Delaware based on Mallinckrodt's breach of a valid and enforceable contract between Genus and Mallinckrodt.

2. Genus is a specialty pharmaceutical company engaged in the development and commercialization of generic and branded pharmaceutical products. In 2013, Genus began developing a cocaine hydrochloride 4% solution product ("GOPRELTO") to be used by physicians as a strong local anesthetic for certain nasal procedures. GOPRELTO was approved by the U.S. Federal Food & Drug Administration ("FDA") in December 2017 and is now available throughout the United States.

3. As part of Genus's development of GOPRELTO, Genus entered into an agreement with Mallinckrodt whereby Mallinckrodt would supply the pharmaceutical grade, raw cocaine

hydrochloride material ("cocaine HCl") to be used as the active pharmaceutical ingredient ("API") in Genus's finished drug product, GOPRELTO.

4. Genus entered the supply agreement with Mallinckrodt in part because Mallinckrodt had submitted a Drug Master File ("DMF") to FDA for its cocaine HCl. A DMF is a submission to FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. By submitting a DMF for cocaine HCl, Mallinckrodt can allow FDA to review its information about cocaine HCl in the context of FDA's review of a drug product, like GOPRELTO, that contains Mallinckrodt's cocaine HCl.

5. Mallinckrodt's DMF 20995 for cocaine HCl includes confidential detailed information about Mallinckrodt's cocaine HCl. Genus does not have access to DMF 20995. Nonetheless, by obtaining a letter of authorization ("letter of authorization") from Mallinckrodt to refer to DMF 20995 in support of Genus's FDA application for GOPRELTO, all of the information in Mallinckrodt's DMF 20995 is available to FDA and can be used in support of Genus's application for FDA approval of GOPRELTO.[1] Genus received a letter of authorization to Mallinckrodt's DMF 20995 in 2014.

6. During FDA's subsequent review of Genus's GOPRELTO product, FDA identified certain deficiencies in Mallinckrodt's cocaine HCl. In response, Genus conducted a battery of proprietary studies on Mallinckrodt's cocaine HCl [redacted]. This type of information would typically be included in the API manufacturer's DMF,

[1] *See* FDA Guidance, Drug Master Files: Guidelines, September 1989 < https://www.fda.gov/drugs/guidances-drugs/drug-master-files-guidelines> (last visited Oct. 22, 2019). ("Letter of authorization means a written statement by the holder or designated agent or representative permitting FDA to refer to information in the DMF in support of another person's submission.")

but in this case, Mallinckrodt's DMF did not contain [redacted]. Because Mallinckrodt did not have this essential information, Genus itself spent a tremendous amount of money conducting numerous studies for over a year to determine whether the cocaine HCl supplied by Mallinckrodt was safe and could be used in Genus's GOPRELTO. Genus's work and discoveries related to cocaine HCl constitute trade secret information belonging solely to Genus.

7. At Mallinckrodt's request, Genus shared with Mallinckrodt Genus's trade secret information regarding Mallinckrodt's cocaine HCl on a highly confidential basis pursuant to written confidentiality and other agreements restricting its use and disclosure. On information and belief, Mallinckrodt then took Genus's trade secret information and added it to Mallinckrodt's DMF 20995 ("enhanced DMF 20995"). Mallinckrodt used Genus's trade secret information to commercially enhance the value of Mallinckrodt's cocaine HCl product. Without Genus's trade secret information, Mallinckrodt's cocaine HCl is deficient and unusable in finished drug products.

8. On information and belief, Mallinckrodt has misappropriated Genus's trade secrets by providing Genus's competitors letters of authorization to the enhanced DMF 20995 that includes Genus's trade secret information without Genus's prior written consent, which has caused and is causing substantial and irreparable harm to Genus.

9. On information and belief, nothing prevents Mallinckrodt from conducting its own research on its cocaine hydrochloride and including [redacted] and information in a separate DMF.

10. Genus seeks, among other things, an order from the Court preventing Mallinckrodt from providing any other party a letter of authorization to the enhanced DMF 20995 because it contains Genus's confidential trade secret information or otherwise providing any third party with

Genus's confidential, proprietary, or trade secret information without Genus's prior written consent. Genus also seeks damages resulting from Defendants' breach of contract conduct as set forth in the Prayer for Relief below.

THE PARTIES, JURISDICTION, AND VENUE

11. Genus is a Pennsylvania corporation organized under the laws of the State of Pennsylvania, with a principal place of business at 514 North 12th Street, Allentown, Pennsylvania 18102.

12. On information and belief, SpecGx LLC is a Delaware limited liability company with a principal place of business located at 385 Marshall Avenue, Webster Groves, Missouri 63119.

13. On information and belief, Mallinckrodt LLC is a Delaware limited liability company with a principal place of business at 675 McDonnell Boulevard, Hazelwood, Missouri 63042.

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Genus asserts a claim for misappropriation of trade secrets under the Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended. This Court has supplemental or pendant jurisdiction over Genus's breach of contract claim pursuant to 28 U.S.C. § 1367 because the breach of contract claim is so related to Genus's federal misappropriation of trade secrets claim that the two form part of the same case or controversy under Article III of the United States Constitution.

15. This Court has personal jurisdiction over both Defendants because they purposefully availed themselves of the Pennsylvania market and have purposefully directed their business activities into this commonwealth, including the Eastern District of Pennsylvania.

16. On information and belief, Mallinckrodt has extensive contacts with Pennsylvania and this District, and Mallinckrodt has deliberately taken advantage of the Pennsylvania market to profit from its business activities.

17. Venue is appropriate in this judicial district pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to this dispute and the damages sustained in this dispute occurred within this district.

STATEMENT OF FACTS

18. Genus currently holds the only FDA-approved New Drug Application ("NDA") for a cocaine HCl drug product in the United States. Specifically, on December 14, 2017, FDA granted approval of NDA 209963, permitting Genus to market the drug GOPRELTO for "the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities in adults."

19. Physicians use GOPRELTO on adult patients as a local anesthetic on the mucous membranes of the nasal cavities during diagnostic procedures and surgeries. In particular, otolaryngologists—commonly referred to as ear, nose, and throats physicians ("ENTs")—and plastic surgeons use GOPRELTO to perform intranasal medical procedures.

FDA's Approval of New Drug Applications and Use of Drug Master Files

20. To gain regulatory approval of any new drug, Genus needed to persuade FDA to approve Genus's NDA for GOPRELTO. The NDA approval process involved Genus providing FDA substantial amounts of material—including highly proprietary and confidential information—related to the efficacy, usefulness, and safety of GOPRELTO.

21. One method of providing FDA information is by referring FDA to a third party's DMF associated with a particular ingredient used in the finished drug product. In this case, Genus provided information about Mallinckrodt's cocaine HCl by referring FDA to Mallinckrodt's DMF

for cocaine HCl. Companies like Mallinckrodt submit DMFs to FDA to provide confidential detailed information about their facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. By submitting a confidential DMF to FDA, Mallinckrodt may be able to keep its trade secret information about its product from everyone, including customers of its product like Genus.

22. To enable Genus to rely on Mallinckrodt's DMF, Mallinckrodt had to provide both FDA and Genus a letter of authorization, permitting FDA to consider information in the DMF while reviewing Genus's application for GOPRELTO. In other words, to the extent a company like Genus seeks FDA approval of an NDA containing Mallinckrodt's cocaine HCl, Genus must first obtain a letter of authorization from Mallinckrodt to refer FDA to Mallinckrodt's DMF for cocaine HCl, and then Genus must send that letter of authorization to FDA to inform FDA that it can use the information in Mallinckrodt's DMF during the review of Genus's NDA for GOPRELTO.

Genus Spent Millions of Dollars to Secure Regulatory Approval of GOPRELTO

23. To gain FDA approval of its GOPRELTO product, Genus performed five clinical trials, comprising 742 human subjects: one Phase 3 pivotal clinical safety and efficacy trial, one pharmacokinetic study, one study on renally impaired patients, one study on hepatically impaired patients, and one thorough cardiac safety study looking for specific heart arrhythmias. Additionally Genus performed ten non-clinical trials to further examine the safety of GOPRELTO and its intended use.

24. [redacted]

[redacted]

25. [redacted]

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

[redacted] This secret

information confers a competitive business advantage to Genus by virtue of not being known to Genus's competitors.

26. According to FDA's definition, a trade secret is "any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." 21 C.F.R. § 20.61(a). Drug application documents are trade secrets. *See, e.g., Citizens Comm'n on Human Rights v. Food and Drug Admin.*, No. 92-5313, 1993 WL 1610471, at *4 (C.D. Cal. May 10, 1993) ("The Court finds that an NDA by definition contains trade secret information because it contains significant information about how a pioneer drug product is formulated, chemically composed, manufactured, and quality controlled."); *Biovail Labs., Inc. v. Anchen Pharm., Inc.*, 463 F. Supp. 2d 1073, 1083 (C.D. Cal. 2006) (holding that an abbreviated new drug application ("ANDA") and amendments are indisputably trade secrets); *Valeant Pharm. Luxembourg S.À R.L. v. Actavis Labs. UT, Inc.*, No. 16-04344, 2018 WL 1469050, at *3 (D.N.J. Mar. 26, 2018) ("In particular, this Court has protected confidential research and development, product testing, formulations, and other trade secret information, including, but not limited to, the confidential nature of ANDAs, drug master files, formulations, and other confidential testing by drug manufacturers." (citation omitted)).

27. Courts have also found certain documents submitted to FDA as part of the NDA and ANDA approval process to be trade secrets, including "information regarding third-party laboratories or contractors/consultants, evidence of the product's safety and effectiveness obtained through preliminary research and human clinical trials, evidence of side effects and their magnitude, . . . the chemical stability characteristics of the drug, the method of drug synthesis, specifications of the finished drug product, the source and specifications for the components and

raw materials, and . . . analytical methods used for the drug and drug components, which are used by the manufacturers to ensure the identity, strength, quality, and purity of the drug substance." *Appleton v. Food and Drug Admin.*, 451 F. Supp. 2d 129, 141, 141 n.7 (D.D.C. 2006) (internal citation omitted) ("[D]ocuments contain[ing] information consisting of drug product manufacturing information, including manufacturing processes or drug chemical composition and specifications" constitute trade secrets and the "[r]elease of this information would reveal how the drug being discussed in the document `is formulated, chemically composed, manufactured, and quality controlled[ ]'" (citations omitted)).

28. [redacted]

29. On November 23, 2016, Genus submitted NDA 209963.[2]

Genus Provided Mallinckrodt Confidential Access to Its Valuable Trade Secrets

30. [redacted]

31. [redacted]

[2] [redacted]

32. [redacted]

33. On information and belief, Mallinckrodt subsequently incorporated Genus's trade secrets [redacted] into its DMF 20995, thereby creating Mallinckrodt's enhanced DMF 20995.

34. On December 14, 2017, FDA approved Genus's NDA 209963, permitting Genus to market and sell its GOPRELTO product.

Genus Made Significant Efforts to Maintain the Confidentiality of its Information

35. Genus takes diligent and reasonable measures as part of its ongoing standard operating procedures to maintain the confidential nature of its information. These measures include, but are not limited to, physical restrictions on areas that contain confidential information, password-protected databases, confidentiality and non-disclosure agreements, and limitations on dissemination of information on a need-to-know basis.

36. Genus took diligent and reasonable measures to maintain the confidential nature of its information throughout Genus's relationships with Mallinckrodt by entering into agreements that protected Genus's information (collectively, the "Agreements"). The Agreements include:

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

f. [redacted]

37. The Agreements protected Genus's confidential information by limiting Mallinckrodt's ability to use the information for purposes other than fulfilling its obligations under the Agreements.

38. The Agreements protected Genus's confidential information by prohibiting Mallinckrodt from disclosing Genus's confidential information to a third party without Genus's prior written consent.

Mallinckrodt Misappropriated Genus's Trade Secrets

39. Without Genus's trade secret information incorporated into Mallinckrodt's enhanced DMF 20995, the FDA found that Mallinckrodt's cocaine HCl was deficient and unusable in finished drug products.

40. On information and belief, Mallinckrodt has illegally provided to FDA and a competitor of Genus a letter of authorization to the enhanced DMF 20995 for cocaine HCl containing Genus's trade secret information. Mallinckrodt is using Genus's trade secret information without the consent of Genus.

41. By providing a letter of authorization by which a party other than Genus may utilize Mallinckrodt's enhanced DMF 20995 containing Genus's trade secret information, Mallinckrodt breaches its confidentiality agreements with Genus prohibiting the use of Genus's confidential information by the third party.

COUNT I - MISAPPROPRIATION OF TRADE SECRETS UNDER THE DEFEND TRADE SECRETS ACT OF 2016 (18 U.S.C. § 1836)

42. Genus realleges and incorporates by reference paragraphs 1 through 41 as if fully alleged herein.

43. This action arises under the Defend Trade Secrets Act of 2016, codified at 18 U.S.C. § 1836, which prohibits threatened and actual misappropriation of trade secrets.

44. Genus owns valuable confidential information and trade secrets, including, but not limited to [redacted]. Pursuant to the Defend Trade Secrets Act of 2016, a "trade secret" means "all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if, (A) the owner thereof has taken reasonable measures to keep such information secret; and (B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information." 18 U.S.C. § 1839(3) (as amended).

45. Genus derives independent economic value, actual or potential, from the information in [redacted] not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from disclosure or use of the same.

46. Genus has expended substantial time, effort, and money in developing [redacted] over the course of many years.

47. Genus has taken reasonable measures to keep such information secret, including, but not limited to, the execution of confidentiality and non-disclosure agreements, password-protected databases, restrictions on physical access to areas that contain confidential information, and limitations on dissemination of information on a need-to-know basis.

48. Mallinckrodt improperly gained access to Genus's confidential information and trade secrets, including, but not limited to [redacted], over the course of a business relationship between Mallinckrodt and Genus, under an obligation to maintain the secrecy of the information.

49. [redacted]

50. As alleged in paragraphs 1 to 49, Mallinckrodt misappropriated Genus's trade secret information by incorporating the information into Mallinckrodt's enhanced DMF 20995, and using the trade secret information, to increase the commercial value of Mallinckrodt's cocaine HCl. Mallinckrodt further misappropriated Genus's trade secret information by providing a letter of authorization to Genus's competitors, thereby allowing Genus's competitors to use Genus's trade secret information without Genus's consent.

COUNT II - BREACH OF CONTRACT

51. Genus re-alleges and incorporates by reference paragraphs 1 through 50 as if fully alleged herein.

52. The Agreements are valid, enforceable contracts.

53. Mallinckrodt voluntarily entered into the Agreements as a prerequisite to its business opportunity and relationship with Genus.

54. The Agreements prohibited Mallinckrodt from using or disclosing Genus's confidential information.

55. The restrictions set forth in the Agreements are reasonable and necessary to protect Genus's legitimate business interests and employment relationships. The restrictions in the Agreements preclude Mallinckrodt from using or disclosing Genus's confidential information.

56. Through its actions, described in the paragraphs above and including but not limited to Mallinckrodt's use of Genus's confidential, proprietary, and trade secret information, Mallinckrodt has breached and continues to breach the express terms of the Agreements that it voluntarily signed.

57. Genus has suffered and continues to suffer damages as a result of Mallinckrodt's breach of its contractual obligations not to use or disclose Genus's confidential information. A direct competitor is now able to obtain the benefit of Genus's trade secrets to accelerate to market competitive products.

58. Through its actions, Mallinckrodt has caused and continues to cause Genus immediate and irreparable harm for which Genus has no adequate remedy at law.

59. Upon information and belief, Mallinckrodt's unlawful conduct alleged herein continues, and there is no indication that it will refrain from continuing such activity in the future.

60. Mallinckrodt will continue such wrongful conduct, in violation of Pennsylvania and/or Delaware law, unless enjoined.

PRAYER FOR RELIEF

WHEREFORE, Genus respectfully requests that this Court:

A. On Count I for Misappropriation of Trade Secrets:

a. Award damages in an amount to be proved at trial;

b. Award Genus its attorneys' fees, its costs and interest;

c. Award exemplary damages based on Mallinckrodt's willful and malicious actions;

d. Grant injunctive relief preventing Mallinckrodt from further disclosing and/or using Genus's confidential information or trade secrets; and

e. Grant such other and further relief as this Court deems equitable, just, and proper.

B. On Count II for Breach of Contract:

a. Grant injunctive relief preventing Mallinckrodt from further disclosing and/or using Genus's confidential information or trade secrets;

b. Award damages including but not limited to contractual and tort damages, in an amount to be proved at trial;

c. Award Genus its costs and interest; and

d. Grant such other and further relief as this Court deems equitable, just, and proper.

JURY DEMAND

Genus demands a trial by jury on all issues which can be heard by a jury.

November 27, 2019

Respectfully submitted,

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s/Travis N. Gery

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EXHIBIT 1

REDACTED

EXHIBIT 2

REDACTED

EXHIBIT 3

REDACTED

EXHIBIT 4

REDACTED

EXHIBIT 5

REDACTED

EXHIBIT 6

REDACTED